

CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CITY OF HUNTINGTON,

Plaintiff,

Civil Action No. 3:17-01362

v.

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

CABELL COUNTY COMMISSION,

Plaintiff,

Civil Action No. 3:17-01665

v.

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

EXPERT REPORT OF JAMES W. HUGHES, PH.D.

August 27, 2020

EXHIBIT 3

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health insurer issues a rebate or credit to the plan sponsor. If healthcare expenditures exceed the funded amount, the plan sponsor reimburses the health insurer up to the stop-loss deductible.²⁰

21. A plan sponsor's costs typically depend on the medical services received by its beneficiaries. Thus, plan sponsors have an incentive to limit these costs by regulating the types and/or quantity of services reimbursed by the payor, limiting services that are not cost effective or medically indicated. In the case of pharmacy benefits, plan sponsors have the ability to determine the prescription drug coverage offered to their members. Plan sponsors can include or exclude specific drugs from the health plan's formulary.²¹ Plan sponsors can also encourage or discourage the use of particular listed drugs through conscientious formulary placement.²²

22. In addition to coverage decisions, payors have access to other tools for managing costs. These tools influence the prescribing of certain medications and limit the number of prescriptions or dosages prescribed of these medications.

23. Plaintiffs are also plan sponsors. The City of Huntington operates a health insurance plan for its employees.²³ Similarly, Cabell County operated a health insurance plan until 2019, when it contracted with PEIA to provide coverage for its employees.²⁴

²⁰ “Level-Funding Growing in Popularity Among Employers,” *Managed Healthcare Executive*, December 23, 2014, available at <http://www.managedhealthcareexecutive.com/managed-care-outlook/level-funding-growing-popularity-among-employers>, accessed on April 30, 2019. See also Priority Health, “Level Funding Frequently Asked Questions,” available at <https://www.priorityhealth.com/agent/group/plans/funding-options/~/media/documents/products/level-funding-faq.pdf>.

²¹ See, e.g., Kaiser 2012, pp. 127–128; Pharmaceutical Care Management Association, “What’s a Formulary?” available at <https://www.pcmanet.org/pcma-cardstack/what-is-a-formulary/>, accessed on April 30, 2019 (“PCMA Formulary”) (“It is ultimately up to the payer client to decide on the exact formulary that will be used in conjunction with its benefits plan, as well as the techniques that will be applied to encourage formulary compliance.”)

²² See, e.g., Deposition of Felice Joseph, July 27, 2020 (“Joseph Deposition”), 133:21–134:8 (“Q. So am I understanding correctly that even non-addictive opioid alternatives may require prior authorization? A. Correct. Q. And that policy is set by PEIA’s PBM? A. That’s one of the programs they offer. PEIA chooses to follow that policy. Q. Could PEIA deviate from that policy and automatically approve non-addictive opioid alternatives? A. PEIA could choose not to require prior authorization on those medications, yes.”) See also Joseph Deposition, 157:17–158:10.

²³ See, e.g., City of Huntington, “Summary of Benefits and Coverage: What this Plan Covers & What You Pay for Covered Services,” available at https://www.cityofhuntington.com/assets/pdf/document-center/Option_U1G-SBC-medical%2Bdrug-Plan_Year_7.1.19-6_.30.20.doc.

²⁴ See, e.g., Travis Crum, “Cabell Switches Health Coverage to PEIA Despite Concerns,” *The Herald Dispatch*, June 14, 2019, available at https://www.herald-dispatch.com/news/cabell-switches-health-coverage-to-peia-despite-concerns/article_5a1cdffd-34ba-5237-89c4-5bf71900f8cf.html, accessed on August 7, 2020.

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24. Two of the largest plan sponsors in West Virginia are West Virginia Medicaid and PEIA, which provide health care coverage to certain patient groups.²⁵

1. West Virginia Medicaid

25. Medicaid is a joint federal and state program that provides health coverage to eligible low-income adults, children, pregnant women, elderly adults, and people with disabilities.²⁶ The Centers for Medicaid & Medicare Services (“CMS”) provide federal oversight of the program. States administer Medicaid according to federal requirements, which mandate the minimum level of benefits offered to beneficiaries and define which patient groups must receive coverage.²⁷

26. The West Virginia state agency, West Virginia Medicaid,²⁸ is operated by the Bureau for Medical Services housed in the West Virginia Department of Health & Human Resources.²⁹ In its Mission Statement, West Virginia Medicaid indicates that it “is committed to administering the Medicaid Program, while maintaining accountability for the use of resources, in a way that assures access to appropriate, medically necessary, and quality health care services for all members.”³⁰

27. A beneficiary’s annual income determines eligibility for Medicaid. Federal laws require states that have expanded access to Medicaid under the Affordable Care Act to cover individuals

²⁵ According to the State of West Virginia’s response to the Opioid Oversight Questionnaire, policies by West Virginia Medicaid and PEIA apply to “approximately 66% of the State’s population.” See DHHR_FEDWV_0209873-900 at 875. See also U.S. Department of Health & Human Services, Office of Inspector General, “FACTSHEET: West Virginia’s Oversight of Opioid Prescribing and Monitoring of Opioid Use,” March 2019, p. 5. This figure is greater than the number of West Virginia Medicaid and PEIA beneficiaries according to other sources. See Exhibit 2.

²⁶ Medicaid.gov, “Medicaid,” available at <https://www.medicaid.gov/medicaid/index.html>, accessed on April 30, 2019.

²⁷ Medicaid.gov, “Eligibility,” available at <https://www.medicaid.gov/medicaid/eligibility/index.html>, accessed on August 25, 2020.

²⁸ Individuals must meet West Virginia Medicaid’s eligibility requirements to receive insurance coverage. See West Virginia Department of Health & Human Resources, Bureau for Medical Services, “Medicaid 101: An Overview of West Virginia’s Medicaid Program,” undated (“Medicaid 101”), pp. 5–7; West Virginia Department of Health & Human Resources, Bureau for Medical Services, “Your Guide to Medicaid 2020,” March 1, 2020, pp. 4–5.

²⁹ Medicaid 101, p. 1.

³⁰ West Virginia Department of Health & Human Resources, Bureau for Medical Services, “Your Guide to Medicaid 2020,” March 1, 2020, p. 2.

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below 138 percent of the federal poverty line.³¹ In 2010, West Virginia Medicaid provided health insurance coverage to around 340,000 beneficiaries.³² In 2014, West Virginia became an Affordable Care Act expansion state, raising the maximum annual qualifying income level.³³ The expansion increased West Virginia Medicaid enrollment by approximately 50 percent—from around 350,000 beneficiaries in 2013 to around 515,000 beneficiaries in 2014.³⁴ In June 2020, West Virginia Medicaid covered around 530,000 beneficiaries.³⁵

28. West Virginia Medicaid administers two types of coverage plans for eligible patient groups:

- Fee-for-Service (“FFS”) plan: Under this plan, healthcare providers and pharmacies bill West Virginia Medicaid directly for each service rendered to a covered patient, including prescription drugs.³⁶ West Virginia Medicaid bears the entire insurance risk;

³¹ HealthCare.gov, “Federal Poverty Level,” available at <https://www.healthcare.gov/glossary/federal-poverty-level-fpl/>, accessed on May 8, 2019.

³² Henry J. Kaiser Family Foundation, “Health Insurance Coverage of the Total Population,” 2010–2018, available at <https://www.kff.org/other/state-indicator/total-population/?dataView=1&activeTab=graph¤tTimeframe=0&startTmeframe=8&selectedRows=%7B%22states%22:%7B%22west-virginia%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>, accessed on August 21, 2020 (“KFF Data about Insurance Coverage”).

³³ Henry J. Kaiser Family Foundation, “Status of State Medicaid Expansion Decisions: Interactive Map,” July 27, 2020, available at <https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/>, accessed on August 4, 2020.

³⁴ Medicaid 101, p. 8. See also Exhibit 2.

³⁵ See Exhibit 2. West Virginia Medicaid’s enrollment numbers fluctuate from month to month and averaged around 545,000 beneficiaries as of July 2020. See Deposition of Cynthia Beane, July 22, 2020 (“Beane 2020 Deposition”), 31:4–14 (“Q. Has -- have those mission – has that mission and those responsibilities changed over time since you’ve worked at BMS? A. Our population has increased over time. With the ACA, we were able to expand our services to include the working poor, and so our population, when I originally came to BMS, was around the 300,000 mark. Now, as duplicated, we serve, you know, sometimes upwards of 600,000 West Virginians a year. Our average enrollment’s around 545,000.”) The average enrollment is at the same level it was in June 2018. See Deposition of Vicki Cunningham, June 15, 2018 (“Cunningham 2018 Deposition”), 66:7–14 (“Q. Then they would have had, what, about 300 or so? A. Yeah -- well, 400,000. With expansion, our population is right around 545,000 members. It’s hard to give an exact number, because people are on and then they don’t qualify anymore so they move off. So it’s hard to give a unique number at any one time.”) Throughout this report, I consider West Virginia Medicaid’s current policies to be consistent with Ms. Cunningham’s testimony from June 2018. In August 2020, Ms. Cunningham testified that, to the best of her knowledge, her testimony from June 2018 is consistent with West Virginia Medicaid’s current policies. See Deposition of Vicki Cunningham, August 24, 2020, (“Cunningham 2020 Deposition”), 21:21–22:18.

³⁶ Cunningham 2018 Deposition, 28:21–29:11 (“Q. So what are your -- what is the Medicaid pharmacy program? A. We are a payer for medications for Medicaid members who need medical care. If members qualify for Medicaid,

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- Managed care organizations (“MCOs”): West Virginia Medicaid offers plans where the MCOs reimburse healthcare providers in exchange for a monthly fee analogous to an insurance premium.³⁷ West Virginia Medicaid and the MCOs share the insurance risk in such plans. The majority of the Medicaid population is required to enroll in an MCO plan rather than the FFS plan.³⁸

29. Exhibit 2 shows the percentage of West Virginia Medicaid beneficiaries enrolled in the FFS plan and each MCO between 2010 and 2020. Relative enrollment in the FFS plan fell from 51.3 percent in 2010 to 19.3 percent in 2020, while total enrollment in West Virginia Medicaid increased from 339,000 beneficiaries in 2010 to 573,000 beneficiaries in June 2016, falling to 528,000 beneficiaries in June 2020. As of 2020, UniCare is the largest of the four MCOs administering Medicaid plans in West Virginia.

30. West Virginia Medicaid has access to the complete medical history of its beneficiaries, including opioid prescriptions.³⁹ All West Virginia Medicaid beneficiaries receive prescription drug coverage through the FFS plan.⁴⁰ As a result, West Virginia Medicaid has access to all

they receive an insurance card, much like a commercial payer would send to their patient. They use that card to obtain treatment from physicians and then physicians write prescriptions for them. And we are responsible for covering those prescriptions. Q. All right. So when you say ‘covering those prescriptions,’ paying for the prescriptions? A. We’re responsible for reimbursing for those prescriptions.”)

³⁷ West Virginia Department of Health & Human Resources, Bureau for Medical Services, “Your Guide to Medicaid 2019,” March 1, 2019, p. 18 (“Mountain Health Trust is the West Virginia Medicaid Managed Care Program. A Managed Care Organization (MCO) is a health care company that contracts with various health care providers to provide members with quality and cost-effective health care.”)

³⁸ West Virginia Medicaid beneficiaries that must enroll in MCO plans include children and their parents or other caretaker relatives, adult Medicaid expansion members, pregnant women, and qualifying individuals receiving Supplemental Security Income. Beneficiaries not eligible to enroll in MCO plans include beneficiaries in long-term care placement, children in foster care, beneficiaries with dual eligibilities (i.e. beneficiaries eligible for both Medicare and Medicaid), beneficiaries in a period of retroactive eligibility, and beneficiaries receiving organ and tissue transplant services. See West Virginia Department of Health & Human Resources, Bureau for Medical Services, “Chapter 527 Mountain Health Trust (Managed Care),” BMS Provider Manual, April 1, 2018, pp. 3–4.

³⁹ A payor has access to all medical claims that were submitted to it, but not to medical claims submitted to other payors (for example, while the beneficiary was not covered by the payor’s health insurance plan). See Cunningham 2018 Deposition, 128:13–15 (“Q. And why is that? A. We don’t have access to other payers’ data or to cash data.”) In general, only the state’s PDMP would include information on all prescriptions of controlled substances dispensed to a patient in the state.

⁴⁰ Medicaid 101, p. 3 (“Importantly, some Medicaid benefits, including pharmacy benefits … are still paid via the fee-for-service delivery system for all Medicaid beneficiaries.”) See also West Virginia Department of Health & Human Resources, Bureau for Medical Services, “Mountain Health Trust (Managed Care),” available at <https://dhhr.wv.gov/bms/Members/Managed%20Care/Pages/default.aspx>, accessed on August 4, 2020; West

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beneficiaries' prescription drug claims reimbursed under the Medicaid program.⁴¹ West Virginia Medicaid also has access to West Virginia's PDMP, which contains the complete prescription drug history—paid by Medicaid, non-Medicaid insurance, or cash—of each Medicaid beneficiary.⁴²

2. Public Employees Insurance Agency

31. The West Virginia Public Employees Insurance Agency was established under the Public Employees Insurance Act of 1971, to provide hospital, surgical, group major medical, prescription drug, group life, and accidental death and dismemberment insurance coverage to active employees of the State of West Virginia and various related State agencies and local governments.⁴³

32. PEIA administers two types of coverage options for eligible patient groups:

- Preferred provider benefit plans ("PPBs"): Under this option, beneficiaries have access to four different plans that are fully self-insured.⁴⁴ All these plans have the same preferred drug list but differ in terms of other features such as copays and

Virginia Department of Health & Human Resources, Bureau for Medical Services, "Chapter 527 Mountain Health Trust (Managed Care)," BMS Provider Manual, April 1, 2018, p. 3.

⁴¹ See, e.g., Deposition of Cynthia Beane, July 19, 2018, 102:16–18 ("Q. And so, does BMS collect pharmacy claims data? A. Yes.")

⁴² Cunningham 2018 Deposition, 87:15–89:10 ("Q. Are you familiar or aware of the West Virginia Board of Pharmacy's Controlled Substance Monitoring Program? A. I am. Q. And that maintains a database that has prescription data? A. Yes. Controlled substances -- ... Q. So the information that's provided to the bureau by the -- through the Controlled Substances Monitoring Program permits the bureau to look at a patient's profile? A. Yes. But only one profile at a time, if there is reason to suspect the patient may be getting an inappropriate number of opioids.") See also Cunningham 2018 Deposition, 88:9–13 ("Q. So their name, Medicaid number, what -- A. It lists the payor for the prescription. I'm not sure that it lists the Medicaid number, but it does list the payor, source of – there's a column for 'Source of Payment.'"); Cunningham 2020 Deposition, 29:5–16 ("Q. Ms. Cunningham, before the break, we were discussing CSAPP [another name for West Virginia's PDMP] and I believe my previous question was why does the CSAPP data provide a more accurate picture of a patient's controlled substance use compared to Medicaid claims data alone? A. Well, it would allow us to know if the patient, either if we had denied a drug because there was an interaction or contraindication, if the patient went ahead and obtained it with cash [...].")

⁴³ State of West Virginia, "Agency: Public Employees Insurance Agency," available at <https://www.wv.gov/pages/agency.aspx?newid=99>, accessed on July 29, 2020.

⁴⁴ State of West Virginia, "Public Employees Insurance Agency," available at https://peia.wv.gov/understand_my_benefits/Pages/default.aspx, accessed on August 19, 2020.

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deductibles.⁴⁵ CVS Caremark is the current pharmacy benefit manager (“PBM”) and has been since July 2016.⁴⁶ Express Scripts was the PBM between 2002 and 2016.⁴⁷ For all PPB plans, PEIA states, “Covered services must be medically necessary or be one of the specifically listed preventive care benefits.”⁴⁸ PEIA does not have its own Pharmacy and Therapeutics Committee (“P&T Committee”) and relies on its PBM to decide on its formulary.⁴⁹

- MCO: Under this option, beneficiaries have access to benefits through an MCO, The Health Plan, which currently provides beneficiaries with three different plan options.⁵⁰ All three plans provide pharmacy benefits using the same formulary but they differ in terms of other features, such as copays and deductibles.⁵¹

33. The vast majority of PEIA beneficiaries are enrolled in a PPB plan. The share of active employees who are enrolled in PEIA’s PPB plan has historically fluctuated around 90 percent. For example, in June 2009, around 88.7 percent of employees were enrolled in a PPB plan and

⁴⁵ See, for example, PEIA, “State of West Virginia PEIA PPB: Plans A, B, C and D,” July 2020 (“PEIA July 2020 PDL”); State of West Virginia, “Public Employees Insurance Agency,” available at https://peia.wv.gov/understand_my_benefits/Pages/default.aspx, accessed on August 19, 2020.

⁴⁶ Joseph Deposition, 60:9–11 (“Q. Who is the pharmacy benefit manager today? A. CVS Caremark.”), 173:24–174:3 (Q. And how long has the PBM -- or how long has CVS been providing these reports to PEIA? A. Since the beginning of their contract, July of 2016.”)

⁴⁷ Joseph Deposition, 60:9–15 (“Q. Who is the pharmacy benefit manager today? A. CVS Caremark. Q. And between the time when Merck-Medco was the pharmacy benefits manager and CVS, have you had other PBMs involved? A. Yes. Express Scripts.”), 91:11–15 (“Q. When did PEIA first implement the prior authorization for prescription opioids that you just mentioned? A. I believe it was in 2002, when Express Scripts became our PBM.”)

⁴⁸ See, e.g., PEIA, “Summary Plan Description PPB Plan C, Plan Year 2020, July 1, 2019–June 30, 2020,” available at https://peia.wv.gov/Forms-Downloads/Documents/summary_plan_descriptions/plan_year_2020/Summary_Plan_Description_C_Plan_Year_2020.pdf (“PEIA C 2020 Plan”), p. 51; PEIA, “Summary Plan Description PPB Plan A, B & D Plan Year 2020 July 1, 2019–June 30, 2020,” available at https://peia.wv.gov/Forms-Downloads/Documents/summary_plan_descriptions/plan_year_2020/Summary_Plan_Description_ABD_Plan_Year_2020.pdf (“PEIA A, B, & D 2020 Plan”), p. 54.

⁴⁹ Joseph Deposition, 140:22–141:3 (“Q. Who decides which drugs should be included on a preferred drug list? A. The PBM Pharmacy and Therapeutics Committee. Q. Does PEIA have its own pharmacy and therapeutics committee? A. No.”)

⁵⁰ The Health Plan, “PEIA,” available at <https://www.healthplan.org/types-plans/employer-plans/peia>, accessed on July 30, 2020.

⁵¹ The Health Plan, “The Health Plan Offers 3 Plan Designs,” available at https://www.healthplan.org/application/files/3715/5190/0496/PEIA_Ben_Chart_2019.jpg, accessed on August 2, 2020.

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11.3 percent were enrolled in an MCO plan; by June 2020, this share of active employees enrolled in PEIA’s PPB plan had slightly increased to 91.1 percent.⁵²

34. Enrollment in PEIA has been relatively stable over time. In June 2009, PEIA provided insurance coverage for 74,540 public employees in West Virginia.⁵³ This number increased to almost 77,000 employees in June 2013 and declined slightly to around 74,000 public employees in June 2020.⁵⁴ Overall, PEIA covers between 220,000 and 240,000 individuals, including spouses and dependents.⁵⁵

35. PEIA has access to its beneficiaries’ pharmacy claims data, including opioid prescriptions.⁵⁶ PEIA does not have access to West Virginia’s PDMP.⁵⁷

36. Since 2019, PEIA has provided insurance coverage to employees of Plaintiff Cabell County.⁵⁸

C. Third-party payors and third-party administrators

37. Third-party payors (“TPPs”) are health insurance companies that market and sell prescription-drug coverage and other health insurance services to individuals, either directly or through a plan sponsor. Under Administrative Services Only contracts, health insurance

⁵² PEIA, “Quarterly Report, December 31, 2010, Fiscal Years 2011–2015,” CCRC Actuaries, LLC, March 2011, p. 5; PEIA, “Quarterly Report, March 31, 2020, Fiscal Years 2020–2024,” Continuing Care Actuaries, July 2020, p. 5.

⁵³ PEIA, “Quarterly Report, December 31, 2010, Fiscal Years 2011–2015,” CCRC Actuaries, LLC, March 2011, p. 5.

⁵⁴ PEIA, “Fiscal Year 2014, Financial Report, Fiscal Years 2014–2019,” CCRC Actuaries, LLC, November 2014, p. 5; PEIA, “Quarterly Report, March 31, 2020, Fiscal Years 2020–2024,” Continuing Care Actuaries, July 2020, p. 5; Joseph Deposition, 52:6–14 (“Q. ... Do you know how much of the 66 percent of West Virginia residents are covered by PEIA versus BMS? A. I know our population is about 163-, 165,000 lives for the PPB plan that is the old indemnity plan. Total lives, we probably have about 220- to 240,000.”)

⁵⁵ Joseph Deposition, 52:6–14 (“Q. ... Do you know how much of the 66 percent of West Virginia residents are covered by PEIA versus BMS? A. I know our population is about 163-, 165,000 lives for the PPB plan that is the old indemnity plan. Total lives, we probably have about 220- to 240,000.”)

⁵⁶ Joseph Deposition, 164:8–10 (“Q. Ms. Joseph, does PEIA collect claims data? A. Yes”)

⁵⁷ Joseph Deposition, 168:22–25 (“Q. Does PEIA have access to the Controlled Substance Monitoring Program database? A. No.”)

⁵⁸ See, e.g., Travis Crum, “Cabell Switches Health Coverage to PEIA Despite Concerns,” *The Herald Dispatch*, June 14, 2019, available at https://www.herald-dispatch.com/news/cabell-switches-health-coverage-to-peia-despite-concerns/article_5a1cdffd-34ba-5237-89c4-5bf71900f8cf.html, accessed on August 7, 2020.

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companies act as third-party administrators, providing claims processing services and enrollment and eligibility services for its plan sponsor clients without taking on any insurance risk.⁵⁹

38. Health insurers may provide various services to plan sponsors depending on their contractual agreement. For example, plan sponsors that insure their own beneficiaries typically use a health insurer to administer the plan sponsor's health plan in an administrative-services-only capacity.⁶⁰ Health insurers will handle claims processing and membership enrollment.⁶¹ When plan sponsors choose to have a fully insured contract with a health insurer, the health insurer is responsible for all covered healthcare expenditures of the plan sponsor's insured members.⁶²

39. Health insurers typically offer multiple plans to plan sponsors and beneficiaries. In particular, the plans can differ in terms of their prescription drug coverage, covered treatments, and cost-sharing arrangements for specific drugs, such as opioids.

40. A formulary summarizes a list of medications covered by the plan.⁶³ Pharmacy and Therapeutics ("P&T") Committees, which consist of health care professionals such as physicians and pharmacists, are responsible for developing, updating and administering the lists of medications covered by each plan.⁶⁴ Each health plan may operate its own P&T Committee and

⁵⁹ See, e.g., J.D. Cleary, "What is a Third Party Administrator (TPA) for Employee Health Benefits?" *PeopleKeep*, February 7, 2012, available at <https://www.peoplekeep.com/blog/bid/111097/What-is-a-Third-Party-Administrator-TPA-for-Employee-Health-Benefits>, accessed on April 30, 2019 ("A Third Party Administrator (TPA) for employee health benefits is a person or organization that performs administrative services (e.g. claim processing, adjudication, record-keeping), usually on behalf of an employer that self-insures health benefits."); Bluhm, p. 747.

⁶⁰ Bluhm, p. 747.

⁶¹ Bluhm, p. 747.

⁶² Bluhm, p. 746.

⁶³ Cole Werble, "Formularies," Health Affairs Health Policy Brief No. 11, September 2017, p.1; American Society of Health-System Pharmacists, "ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System," 2008, pp. 215–217 ("ASHP Statement") at p. 215.

⁶⁴ For example, West Virginia Medicaid's P&T Committee consists of up to 15 active healthcare professionals who advise the Secretary on the selection of drugs for the PDL. See West Virginia Department of Health & Human Resources, Bureau for Medical Services, "Pharmaceutical and Therapeutics Committee," available at <https://dhhr.wv.gov/bms/BMS%20Pharmacy/PharmTheraComm/Pages/default.aspx>, accessed on August 5, 2020. For PEIA, "Drugs on the WVPDL are determined by the CVS Caremark Pharmacy and Therapeutics Committee. The committee, made up of physicians, meets quarterly to review the medications currently on the Formulary, and to evaluate new drugs for addition to the Formulary." See PEIA A, B, & D 2020 Plan, p. 78.

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formulary, or it may adopt a formulary constructed by the insurer or PBM.⁶⁵ Plan sponsors have the ability to modify these formularies to suit their particular goals.⁶⁶

41. Formularies typically categorize drugs into tiers, where different tiers have different cost-sharing arrangements.⁶⁷ For example, the bottom tier, which tends to include mostly generic medications, will have the lowest copayment or co-insurance requirement for the patient. The second tier may contain favored brand name medications, while the remaining tier or tiers include other brand name medications or specialty drugs with the highest copayment or co-insurance levels.⁶⁸ By placing drugs or treatments on different tiers, plan sponsors or insurers can incentivize and influence the prescribing of certain medications over others.⁶⁹

42. West Virginia Medicaid and PEIA are both plan sponsors and TPPs for certain beneficiaries. In particular, West Virginia Medicaid and PEIA directly provide health insurance for their beneficiaries covered in the FFS or PBB plans, respectively. For beneficiaries covered through the MCO plans, West Virginia Medicaid and PEIA contract with TPPs to provide insurance coverage.

43. In West Virginia, as of 2018, approximately 94 percent of the population has health insurance.⁷⁰ Employer sponsored plans insure 44 percent of the population.⁷¹ West Virginia Medicaid and Medicare cover about 26 percent and 19 percent of the population, respectively.⁷² Approximately three percent purchased health insurance directly from an insurance company,

⁶⁵ Academy of Managed Care Pharmacy, “Pharmacy & Therapeutics Committee,” February 2015, p. 4; Express Scripts, “How We Build a Formulary,” November 12, 2018, available at <http://lab.express-scripts.com/lab/insights/drug-options/how-we-build-a-formulary>, accessed on April 22, 2019.

⁶⁶ PCMA Formulary (“It is ultimately up to the payer client to decide on the exact formulary that will be used in conjunction with its benefits plan, as well as the techniques that will be applied to encourage formulary compliance.”)

⁶⁷ PricewaterhouseCoopers, “Study of Pharmaceutical Benefit Management,” HCFA Contract No. 500-97-0399/0097, June 2001 (“HCFA”), pp. 17–18, 66.

⁶⁸ Health insurers may also offer formularies with more than three tiers. See, e.g., CareSource, “Marketplace Plan: Drug Formulary, West Virginia,” 2020, p. ii (“Tiered Medications: The CareSource Formulary has up to six levels or tiers, including tiers 0, 1, 2, 3, 4 and 5. Some benefit designs only have five tiers.”)

⁶⁹ HCFA, p. 18 (“An incented formulary applies differential co-pays or other financial incentives to influence patients to use, pharmacists to dispense, and physicians to write prescriptions for formulary products.”)

⁷⁰ KFF Data about Insurance Coverage.

⁷¹ KFF Data about Insurance Coverage.

⁷² KFF Data about Insurance Coverage.

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and about one percent are covered through the military.⁷³ The remaining six percent of the population were uninsured.⁷⁴

44. TPPs and plan sponsors reimburse the vast majority of prescription drug benefits in West Virginia. In 2019, private and public payors reimbursed almost 96 percent of all prescriptions filled by pharmacies in West Virginia, while only about four percent of prescriptions were paid in cash.⁷⁵

45. Note that even patients who pay for their prescriptions in cash may be affected by the coverage and utilization management decisions of large insurers. In particular, the decisions of large TPPs can influence physician prescribing behavior for all of their patients, affecting physician choices for cash-paying patients and patients of other health insurance plans. For example, academic research has shown that the status of a drug on Medicaid’s preferred drug list (“PDL”) can “spill over” to non-Medicaid patients.⁷⁶

D. Pharmacy benefit managers

46. Pharmacy benefit managers (“PBMs”) began as pharmacy claims processors for health insurers in the late 1970s.⁷⁷ Over time, PBMs have taken on increased pharmacy benefit management responsibilities for insurers. PBMs are now involved in designing formularies, monitoring trends in prescription drug use, and proposing cost control measures, in addition to

⁷³ KFF Data about Insurance Coverage.

⁷⁴ KFF Data about Insurance Coverage.

⁷⁵ Henry J. Kaiser Family Foundation, “Number of Retail Prescription Drugs Filled at Pharmacies by Payer,” 2019, available at <https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/?dataView=0¤tTimeframe=0&sortModel=%7B%22collId%22:%22Location%22,%22sort%22:%22asc%22%7D>, accessed on August 19, 2020.

⁷⁶ See, e.g., Virabhak Suchin and Judith Shinogle, “Physicians’ Prescribing Responses to a Restricted Formulary: The Impact of Medicaid Preferred Drug Lists in Illinois and Louisiana,” *American Journal of Managed Care* 11(Special Issue), 2005, pp. SP14–SP20 (“Virabhak and Shinogle 2005”), at SP18; Wang Richard Y. et al., “Impact of Maine’s Medicaid Drug Formulary Change on Non-Medicaid Markets: Spillover Effects of a Restrictive Drug Formulary,” *American Journal of Managed Care* 9(10), 2003, pp. 686–696 at p. 686.

⁷⁷ Robert P. Navarro, *Managed Care Pharmacy Practice* (Sudbury, MA: Jones and Bartlett Publishers, 2009) (“Navarro”), pp. 96–97.